

# Compression therapy device & accessories

# Model 701A User manual



April 2008

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#### 1 General

The information listed in this user manual will assist you in using the Petite Basic System (PBS) device and accessories to obtain maximum benefits from the treatment. Should you have any questions or require further information, please do not hesitate to contact your local dealer.

The Petite Basic System is a non-invasive intermittent sequential external pneumatic compression system that aids in the reduction and management of peripheral edema, such as lymphedema and ulceration associated with venous insufficiency.

#### 1.1 Indications

- Venous stasis ulcers
- Reduce and manage peripheral edema
- Venous insufficiency
- Lymphedema

#### 1.2 Contraindications

Compression is not recommended in the following conditions.

- Known or suspected deep venous thrombosis
- During the inflammatory phlebitis process
- During episodes of pulmonary embolism
- Pulmonary edema or congestive heart failure
- Severe arteriosclerosis or other ischemic vascular disease
- Any circumstance where increased venous and lymphatic return is undesirable



#### Warning:

Federal law (U.S.A.) restricts this device to sale by, or on the order of, a physician.

# 1.3 The Petite Basic System cycle

The PBS is an intermittent sequential external pneumatic compression system that aids in the reduction and management of peripheral edema, such as lymphedema and ulceration associated with venous insufficiency. The treatment cycle consists of inflation and pause time. During inflation, the cells inside the compression sleeve are inflated one after the other from distal to proximal. The time required for inflation will depend on the pressure level selected and on the size of the treatment sleeve. When all four cells have reached the required pressure, all of the cells will deflate, followed by the pause time after which the inflation cycle repeats. The pressure and the pause between cycles are adjustable.

# 1.4 Specifications and Dimensions

Specifications		Dimensions	
Model	701A	Height	3.9 inches
Catalog No.	L10000A6	Length	10.2 inches
Class	II (double isolation)	Width	5.1 inches
Pressure range	20~80 mmHg	Net Wt.	5.1 lb.
Voltage	115V ~ 50/60 Hz		
Power consumption	11W		
Fuses rating	2A		

**Note:** Although the device is Class II, it is equipped with a functional grounding (three-pin plug), for safety purposes.

# 1.5 Symbols on devices

Symbol	Explanation	Location
$\wedge$	Attention!	On bottom of
<u> </u>	Refer to manual	air pump
$\bigcap_{\mathbf{i}}$	Consult instructions before use	On sleeve's tag
<b>†</b>	Level of protection - type BF equipment	
	Temperature limitations for storage and/or transport of the device	On carton box
2007	Date of manufacture	On bottom of air pump
Accompanied by the name and the address of the manufacturer		On bottom of unit and on sleeve label
MEDICAL ELECTRICAL EQUIPMENT UL 60601-1 and CANCSA C22.2 No. 601.1	Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1.	On back of unit

#### 1.6 Safety features

# 1.6.1 In case of power failure

In the event of power failure, the pneumatic control unit is designed to deflate all the air from the sleeves automatically.

#### 1.6.2 One-way hose connection

In order to prevent wrong connection of the air hose bundle to the device, which will cause improper inflation order (sequence) of the sleeves, the connector is designed for one-way connection. Proper connection can only be done when the connector plug is inserted in the proper direction, with the connector's "*The* Petite Basic System" logo facing up.

The hose end fittings (on the sleeve side of the hose bundle) are numbered from 1 to 4, indicating the order in which they are to be connected to the sleeve, from distal to proximal, corresponding to the numbers 1 through 4, next to the air inlets on the sleeve. Each number also has a specific color, both on the hoses' end and on the sleeve's air inlets.

#### 1.6.3 Overload Protection Fuses

The device is equipped with two overload fuses, on each of the power lines ("~" and "0").

#### 1.6.4 "Lock" button

The "Lock" button fixes the pressure adjustment knob in place, preventing the pressure knob from being accidentally reset to an inappropriate pressure.

# 2 Main components

#### 2.1 Device Unit

This device is powered by electricity, provided by a wall outlet with a grounding connection.

It supplies compressed air in fixed cycles at regulated pressures. The power unit is able to simultaneously operate two sleeves with 4 air compartments each.

#### 2.2 Hose Bundle

The hose assembly that transfers compressed air from the device unit to the sleeves. It includes 4 hoses, a connector that attaches to the corresponding receptacle of the device unit and 4 numbered and color-coded end fittings that attach to the sleeve.

## 2.3 Pronged Plug

Plug used to seal off the unused outlet of the device unit, when only one limb is treated.

#### 2.4 Sleeves

Each zipper sleeve has 4 air compartments and uses cyclic air pressure. Different sizes of sleeves are available,

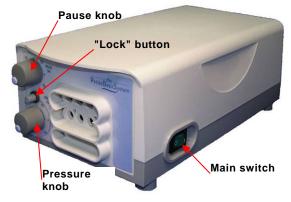
# 2.5 Sleeve Expanders

If necessary, a zipper expander may be added between the two sides of the zipper to increase the sleeve's circumference.

# 2.6 Inner Cotton Hygienic Sleeve

A tubular cotton inner sleeve, worn under the treatment sleeve for hygienic purposes. The inner cotton sleeve is a one-piece tubular bandage, much like an open-ended stocking, that fits over the limb.

Figure 1 – the Petite Basic System components



a. Device unit



b. Hose bundle



c. Prong plug



d. Cotton inner hygienic sleeve



e. Leg sleeve



f. Arm sleeve



g. Expander

# **3 Operating the Petite Basic System**

## 3.1 Setting up the Petite Basic System device

Place the Petite Basic System on a flat table surface or suspend it on the end of a bed with the attached hooks. The device should be easily reached by the patient. Be sure the device is securely positioned to ensure that the device will not slip or fall. If the device is hung from the bed rail, it is recommended to center the device in the middle of the rail.

## 3.2 Attaching the air hoses to the sleeves

Attach the air hoses to the sleeve by inserting each hose into its appropriate air inlet, matching the numbers and colors on both the end fittings of the hoses and the sleeve's inlets. Air inlet number 1 is always the farthest one from the body.

# 3.3 Putting on the sleeve

First cover the limb(s) with the inner cotton sleeve(s), then put on the Petite Basic System sleeve(s) as follows:

- a. **For leg sleeves:** Insert foot into the boot. Pull the sleeve towards knee, extending it to its maximum length, close the zipper, starting from the bottom.
- b. For arm sleeves: Zip the sleeve closed at least part of the way up before inserting your arm. Make sure the zipper is facing up, and that the cut-out area is under your armpit. Zip the sleeve closed. Support your arm on an armrest or a pillow during treatment. If the sleeve tends to slide down during treatment, use the optional belt. To use the belt, attach one end of the belt to the snap closure on the sleeve, at the back, then pull on the sleeve, zip it closed, pull the belt around your body under the arm not being treated and fasten it to the other snap closure at the front. Correctly fastened, the belt should cross from the shoulder of the arm being treated, across the chest and under the arm not being treated. Tighten the belt so that it fits just enough to keep the sleeve from slipping down.
- c. During treatment, the zipper should be closed and left closed with the hoses attached. The patient should be able to slip sleeve off and pull on again for each use without unzipping the sleeve each time. (Note: After use, the sleeve will deflate within a short time, enabling it to be removed easily).



#### Note:

Do not use any sleeve other than the Petite Basic System sleeves, made especially for the Petite Basic System device.

## 3.4 Connecting the air hoses to the device

Securely insert the hose bundle connectors - with the Petite Basic System logo facing up - into one of the air sockets on the Device unit (it does not matter which one). If only one sleeve is to be used, remove the Pronged Plug from its storage socket and place it into the unused air outlet. This will prevent air from escaping through the unused socket. Make sure the air hoses are not bent, kinked or pinched.



#### Note:

When only one sleeve is used, the second outlet must be plugged. Otherwise the device will stop working and the alarm buzzer will beep.

# 3.5 Operating instructions (See Figure 2)

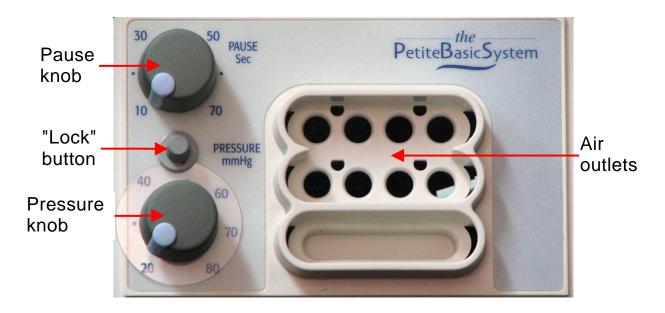


#### Note:

When using the device, do not use any pressure other than the pressure prescribed by your physician. Treatment time should not exceed that prescribed by your physician. If you have any questions, contact your physician.

In the case of a power failure, turn the device OFF and remove the electrical cord from the wall outlet.

Figure 2 – the Petite Basic System - general view of front panel



- a. Connect the power cord to an electrical outlet.
- b. The first time you use the device, set the Pressure and the Pause knob to their minimum settings.
- c. Turn the device ON and wait for a few cycles to become accustomed to the treatment sensations. Note that the first inflation cycle may take a longer time to fill, especially if you are using two sleeves.
- d. Next, set the pressure and pause time according to your physician's instructions. Then lock the pressure knob by turning the "Lock" knob clockwise. This will prevent accidental tampering with the pressure knob. If you ever need to change, the pressure, simply loosen the "Lock" knob, change the pressure settings, and re-tighten the "Lock" knob.
- e. Continue the treatment for the time ordered by your physician.



#### Note:

If your dealer has preset and locked the pressure settings according to your physician's instructions, please omit steps b through d in the instructions above. Simply turn the device on and continue treatment for the time ordered by your physician. Note that the first inflation cycle may take longer to complete, especially if you are treating two limbs at the same time. The subsequent cycles will be shorter.



#### Note:

For larger sleeves, a longer pause time will be necessary to ensure sufficient deflation of the sleeves between cycles. The device will not inflate the sleeve unless the air from the previous cycle has adequately emptied. If the pause time has been set too short for adequate deflation, the device will automatically double the pause time. To prevent this, increase the pause time slightly and try again.

#### 3.6 End of treatment

At the end of the treatment, shut the unit OFF. Remove the sleeve(s) from the limb(s).

You do not have to disconnect the hoses from the sleeves or unzip the sleeves after each use. (If you travel with the device, the hoses should be disconnected from the sleeves). If you wish to disconnect the hoses from the sleeve, gently work the end fitting free from the air inlet using a twisting / pulling motion.



#### **Note:**

- 1. The treatment should be pleasant and relaxing.
- 2.If the device stops working and the warning signal sounds, it means that the time needed to fill up the sleeve is too long. Usually this is due to air leakage because the sleeves or hoses are not properly connected. If this happens, turn the device OFF, and
  - a. Check that all the hose ends are correctly inserted into the air inlets.
  - b. Check that the hose connectors are properly connected to the air outlets on the device.
  - c. If using only one sleeve, make sure that the unused outlet is plugged with the prong plug.

If all the connections are OK and the problem persists, contact your dealer.

3. In the case of a power failure, turn the device OFF, take off the sleeve, and remove the electrical cord from the wall outlet.

#### 4 Maintenance



#### Warnings:

- 1.Only an authorized technician should open the device.
- 2. Before cleaning the device, disconnect the power cord from the electrical wall outlet.

## 4.1 Cleaning the device

Gently wipe the outside of the device using a damp, nonabrasive cloth.

Do not spill any liquids on the device.

# 4.2 Cleaning the sleeves

- Gently wipe the sleeve using a soft cloth, warm water (not exceeding 40°C (100°F)) and a non-allergenic cleaning liquid. Do not allow water to enter the air inlets of the sleeve!
- Wipe dry using a soft towel only.
- When dry, the sleeve may be wiped down using a hospital-grade antiseptic or antimicrobial sanitizing lotion.



#### Warnings:

Do not dry clean, hand or power wring, iron, tumble or force heat dry.

Do not use bleach! Clean only according to instructions.

# 4.3 Storage

- 1 Store in a dry, shaded place at temperatures between -20°C to +70°C.
- 2 The device should be stored after rolling up the power cord. Do not bend the cord.
- 3 Since the sleeve is inflated by compressed air, it must remain airtight. Therefore, avoid contact with pins, needles and any other sharp objects or instruments. If one of the cells is damaged, the sleeve must be replaced.
- 4 Store the sleeve flat, without folding.
- 5 The hoses should be kept untwisted and unfolded.

## 4.4 Transport

Transport in original packaging, at temperatures between -20°C to +70°C.

# 4.5 Troubleshooting



Note:

Before continuing, check all accessories visually for any defects.

**Table 1 - Troubleshooting guide** 

Symptom	Possible cause	Corrective action
The device is not working.	No electricity.	Check the electrical wall outlet.
	Power cord.	Check the power cord visually for any defects.
	Fuses.	Check the fuses and replace if necessary.  If they burn out again, contact your dealer.
The device starts working and stops immediately.	The air cannot move through the hose bundle.	Check hose bundles for kinks, twists and folds.
One sleeve inflates but the second one does not.	The second sleeve does not receive air.	Check its hose bundle for kinks, twists and folds.
The device stops working and buzzer beeps.	Hose bundle is not connected properly to sleeve or device, or prong plug is not inserted into unused air outlet.	Check and fasten all air connections. When treating only one limb, always plug the unused air outlet with the prong plug provided with the device. If all air connections are OK and problem persists, contact your dealer.
The device works at a very low pressure, regardless of the pressure set by the	Defective sleeve.	Replace sleeve and check again.
user.	An internal problem.	Contact your dealer.
An irregular noise.	Transferring of vibrations to the table or the patient's bed.  An internal problem.	Make sure the device is standing on all four of its bumpers, or is hung properly on its hooks while supported by the two rear bumpers.  Contact your dealer.

# 5 Manufacturer details and warranty

#### 5.1 Manufacturer address

Mego Afek AC Ltd. • Kibbutz Afek, 30042 • Israel

# 5.2 Warranty

- a. Mego Afek AC Ltd. warrants the Petite Basic System and its sleeves to be free of defects in materials and workmanship.
- b. This warranty applies as follows:
  - For devices: for a period of twelve (12) months from date of purchase.
  - For sleeves: for a period of six (6) months from date of purchase.
- c. This warranty does not include or cover malfunctions caused by unreasonable use, non-compliance with user and maintenance instructions, or damage caused by unauthorized or unqualified repairs.

# 6 Representative in USA

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